APR - 9 2012

510(k) Summary

MEDTRONIC Sofamor Danek
CAPSTONE CONTROL™ SPINAL SYSTEM
February 3, 2012

I.	**Company:**	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 (901) 396-3133
II.	**Contact:**	Julie Bassett Principal Regulatory Affairs Specialist Telephone: (901) 399-3248 Fax: (901) 346-9738
III.	**Proposed Proprietary Trade Name:**	CAPSTONE CONTROL™ Spinal System
IV.	**Classification Names:**	Intervertebral Body Fusion Device (21 CFR 888.3080)
	Class:	II
	Product Code:	MAX

V. **Description:**

The CAPSTONE CONTROL™ Spinal System consists of PEEK cages of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar

interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft.

The CAPSTONE CONTROL™ Spinal System implants will be available in heights of 8mm to 18mm, lengths of 22mm, 27, mm, and 32mm, and widths of 9mm or 10mm. In addition, the implants will be available with 0°, 6°, 12°, and 18° of lordosis.

VI. Indications for Use:

The CAPSTONE CONTROL™ Spinal System has the same indications for use as the predicate CAPSTONE® Spinal System. The CAPSTONE CONTROL™ Spinal System is indicated for interbody fusion with autogenous bone graft in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

VII. Summary of the Technological Characteristics:

The CAPSTONE CONTROL™ Spinal System has the same fundamental technology as the predicate CAPSTONE® Spinal System. The CAPSTONE CONTROL™ Spinal System implants (subject device) and the CAPSTONE® Spinal System implants (predicate device), are both made from Zeniva ZA-500 PEEK material with tantalum markers. The predicate and subject devices are

also both convex, bullet-nosed interbody devices designed to contain graft material and facilitate a fusion between two vertebral bodies.

VIII. Identification of Legally Marketed Devices:

The CAPSTONE CONTROL™ Spinal System has the same indications for use and fundamental scientific technology as the predicate, CAPSTONE® Spinal System (K073291, SE 4/24/2008 and K103731, SE 07/18/2011).

Additional predicates are being used to demonstrate that the additional size options and features are not new and currently exist in other legally marketed devices. These predicates include:

- K111512 – BoneBac™ T-PLIF Invertebral Body Fusion Device System by Thompson MIS (SE 10/26/2011)
- K033926 – HOURGLASS® Spinal System by Medtronic (SE 10/26/04)
- K071795 - CoRoent™ by Nuvasive, (SE 12/4/2007)
- K090353 - PERIMETER® Spinal System by Medtronic (SE 8/29/2009)
- K094025 – CRESCENT™ Spinal System by Medtronic (SE 4/26/2010)

IX. Discussion of Non-Clinical Testing:

In order to demonstrate substantial equivalence to the predicate devices, FDA's Guidance document, Class II Special Controls Guidance Document: Intervertebral Body Fusion Device issued June 12, 2007, was used. In addition, mechanical testing was conducted on the subject CAPSTONE CONTROL™ Spinal System in accordance with ASTM F2077-11: Test Methods for Intervertebral Body Fusion Devices and ASTM F2267-04: Standard Test Method for Measuring Load Induced Subsidence of the Intervertebral Body Fusion Device under Static Axial Compression. These tests included static compression testing, dynamic compression fatigue testing, static compression shear testing, dynamic compression shear fatigue testing, and subsidence. Due

to the "insert and rotate" feature of the implants, rotational testing was also performed. All testing met the predetermined acceptance criteria and demonstrated that the subject device was as safe and effective as the predicate devices.

XI. Conclusion:

Based on the risk analysis, test results, and additional supporting documentation provided in this pre-market notification, the subject CAPSTONE CONTROL™ Spinal System is the subject device is as safe and effective as the predicates, CAPSTONE® Spinal System (K073291, SE 4/24/2008 and K103731, SE 07/18/2011), K111512 – BoneBac™ T-PLIF Invertebral Body Fusion Device System by Thompson MIS (SE 10/26/2011), K033926 – HOURGLASS® Spinal System by Medtronic (SE 10/26/04), K071795 - CoRoent™ by Nuvasive, (SE 12/4/2007), K090353 - PERIMETER® Spinal System by Medtronic (SE 8/29/2009), and K094025 – CRESCENT™ Spinal System by Medtronic (SE 4/26/2010).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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% Ms. Julie Bassett
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APR - 9 2012

Re: K120368
Trade/Device Name: CAPSTONE CONTROL™ Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: February 3, 2011
Received: February 6, 2012

Dear Ms. Bassett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin L Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K120368

Device Name: CAPSTONE CONTROL™ Spinal System

Indications for Use:

The CAPSTONE CONTROL™ Spinal System is indicated for interbody fusion with autogenous bone graft in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120368